K021645

JUN 2 6 2002

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Sterngold is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Sterngold chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: **ERA Implant**

Sponsor: Sterngold
23 Frank Mossberg Drive
P.O. Box 2967
Attleboro, MA 02703-0967
Registration #2921595

Device Generic Name: Endosseous Dental Implant

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class III.

Predicate Devices: ***Refer to Attachment C***
Manufactured by: Refer to Attachment C

Product Description: The Sterngold ERA Implant is a titanium Alloy threaded screw intended to have a simpler and quicker installation procedure than is currently used for conventional implants. This design will enable the physician to quickly and efficiently establish an inexpensive temporary restorative solution to patients undergoing longer-term, conventional implantation therapy.
The Sterngold ERA Implant is available in 2.2 mm diameter and lengths of 10 mm, 13 mm, and 15 mm. The head features two designs – One implant featuring our ERA abutment interface with 1.2mm, 3mm, 4mm cuff heights and offers a 0°, 5°, 11°, and 17° angle abutments. The second implant with cuff heights of .76mm, 2mm, 3mm, and 4mm with no angles.

Indications for Use: The ERA Implant is indicated for Use as a temporary support, when placed between traditional implants to stabilize a denture during healing period, and to restore the patient's chewing function.

Safety and Performance:
This submission is a Special 510(k): Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Sterngold has provided information to demonstrate conformity with FDA's guidance document entitled Premarket Notification 510(k): Regulatory Requirements for Medical Devices.

Conclusion: Based on the indications for use, technological characteristics, and comparison to predicate devices, the *ERA Implant* has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Maria Rao
Quality and Regulatory Manager
Sterngold
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703-0967

JUN 2 6 2002

Re: K021045
Trade/Device Name: ERA Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: March 25, 2002
Received: April 1, 2002

Dear Ms. Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021045

Device Name: ERA Implant

Indications for Use:

The ERA Implant is intended for surgical placement in edentulous anterior regions of the maxillary and/or mandibulary arch to provide temporary support and permit immediate stability and ongoing fixation of new or existing crown and bridge applications, for full or partial dentures, with minimal invasive surgical intervention.
Sterngold's ERA Implant is indicated for use as a temporary, when placed between traditional implants to stabilize a denture during healing period.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021045